IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of: Ronald W. MARSH, et al.	
Application No.: 10/728,547	
Filed: December 5, 2003	Group Art Unit: 3767 Examiner: Phillip A. Gray Confirmation No.: 8789
For: VARIABLE EXTENSION COMBINED SPINAL/EPIDURAL NEEDLE SET AND METHOD FOR ITS USE	

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

APPEAL BRIEF

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A. Real Party in Interest

The real party in interest is Becton, Dickinson and Company, the assignee of record.

B. Related Appeals and Interferences

Neither Appellant nor its agents are aware of any prior or pending appeals, judicial proceedings or interferences which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

C. Status of Claims

Claims 1-20 were finally rejected in an Office Action mailed on May 14, 2007 (the "Final Office Action") under 35 U.S.C. § 103(a). The rejection of claims 1-20 are appealed. A copy of the claims on appeal are in the Appendix of this Brief.

D. Status of Amendments

No amendments have been filed subsequent to the mailing of the Final Office Action.

E. Summary of Claimed Subject Matter

The claimed subject matter encompasses hypodermic needles intended for administration and withdrawal of fluids to the spine of a patient.

Independent claim 1 is directed to an epidural needle which comprises an elongate tube defining a longitudinal axis having a proximal end, a distal end and an axial hollow bore having an inside diameter therethrough. (page 4, lines 5-7; page 6, lines 21-26.)[1] The distal end is a sharpened tip suitable for penetrating a patient's tissue. (page 10, lines 7-8.) A hub having a proximal end, a distal end and an open passageway therethrough is attached to the proximal end of the elongate tube so that the hollow bore of the elongate tube is in fluid communication and substantial axial alignment with the open passageway, and the hub further has a cavity therein disposed between the proximal end and the distal end of the hub. (page 4, lines 7-13; page 6, line 26 – page 7, line 4.) A resilient member is permanently mounted within the hub having an opening therethrough defining an inner diameter and disposed in the cavity so that the opening is substantially axially aligned and in fluid communication with the open passageway. (page 4, lines 13-16; page 7, lines 1-4.) A clamp selectively movable between an open position is provided wherein the inner diameter of the resilient member is substantially unaffected, and a clamp position wherein the clamp causes a strain to at least a portion of the resilient member thereby reducing, but not occluding, the inner diameter of the opening through at least a portion of the resilient member. (page 4, lines 16-21; page 7, lines 5-11.)

Independent claim 10 is directed to a combined spinal epidural needle set comprising an epidural needle including an elongate tube defining a longitudinal axis having a proximal end, a distal end and an axial hollow bore having an inside diameter therethrough (page 4, lines 5-7; page 6, lines 21-26.) The distal end is a sharpened tip suitable for penetrating a patient's tissue. (page 10, lines 7-8.). The epidural needle has a

[1] Page and paragraph designations refer to those found in the originally filed specification.

hub having a proximal end, a distal end and an open passageway therethrough, the hub being attached to the proximal end of the elongate tube so that the hollow bore of the elongate tube is in fluid communication and substantial axial alignment with the open passageway and the hub further has a cavity disposed between the proximal end and the distal end of the hub. (page 4, lines 7-13; page 6, line 26 – page 7, line 4.) A resilient member is provided that member has an opening therethrough defining an inner diameter and is disposed in the cavity so that the opening is substantially axially aligned and in fluid communication with the open passageway. (page 4, lines 13-16; page 7, lines 1-4.) A clamp having a releasable latch is disposed about the resilient member, the clamp being selectively movable between an open position wherein the inner diameter of the resilient member is substantially unaffected and a clamp position wherein the clamp causes a strain to the resilient member thereby reducing the inner diameter of the opening through the resilient member. (page 4, lines 16-21; page 7, lines 5-11.) A spinal needle having an outside diameter less than the inside diameter of the hollow tube is disposed within the hollow bore, and a practitioner using the epidural needle to position the spinal needle may freely axially move the spinal needle within the hollow bore with respect to the epidural needle and fix a position of the spinal needle relative to the epidural needle by the reduction of the inner diameter opening through the resilient member to a diameter less than the outside diameter of the spinal needle by movement of the clamp to the clamp position thereby to grasp releasably the spinal needle sufficiently to fix the position of the spinal needle with respect to the epidural needle, wherein the spinal needle is not occluded in the clamp position. (page 4, lines 24-31; page 8, lines 7-17.)

Independent claim 19 is directed to a needle including an elongate tube defining a longitudinal axis having a proximal end, a distal end and an axial bore having an inside diameter therethrough, wherein the distal end is a sharpened tip. (page 4, lines 5-7; page 6, lines 21-26.; page 10, lines 7-8.) The needle further has a hub having a proximal end, a distal end and an open passageway therethrough, the hub being attached to the elongate tube so that the hollow bore of the elongate tube is in fluid communication and substantial axial alignment with the open passageway, the hub further having a cavity disposed therein between the proximal end and the distal end of the hub. (page 4, lines 7-

13; page 6, line 26 – page 7, line 4.) A resilient member, distinct from the elongate tube, having an opening, at least in part, therethrough defining an inner diameter is disposed in the cavity so that the opening is substantially aligned and in fluid communication with the open passageway, wherein the resilient member fixedly secured within the cavity and restrained from axial displacement with respect to the hub. (page 4, lines 13-16; page 7, lines 1-4.) The needle further includes a clamp selectively moveable between a first position wherein the resilient member is undeformed, and a second position wherein the resilient member is deformed such that the inner diameter of the opening is changed through at least a portion of the resilient member, but the inner diameter of the opening is not occluded. (page 4, lines 24-31; page 8, lines 7-17.)

F. Grounds of Rejection to be Reviewed on Appeal

Whether claims 1-20 are unpatentable under 35 U.S.C. § 103(a) over McWha et al. (U.S. Patent No. 5,480,389; "McWha") in view of Schaffer et al. (U.S. Patent No. 5,429,616; "Schaffer").

G. Argument

Claims 1-20 stand finally rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over McWha in view of Schaffer.

Appellant respectfully asserts that (1) a *prima facie* case of obviousness has not been established; (2) the combination of McWha and Schaffer does not result in the claimed invention, nor does the combination function in the same fashion as the claimed invention; and (3) the proposed modification to Schaffer destroys the intended function of Schaffer.

1. Summary of the Prior Art Applied

A. McWha, U.S. Patent No. 5,480,389

McWha discloses an apparatus for adjusting the length of a combined spinal epidural needle. With reference to Figure 2, McWha teaches a spinal epidural needle set comprising an epidural needle (14) with a sharpened distal end (14a), a spinal needle (12) located within the epidural needle (14) and an attached hub (10)

McWha describes at column 11, lines 14-67 how to operate the combined spinal epidural needle. The epidural needle (14) is inserted into the patient until the distal point (14a) is positioned in an appropriate location within the epidural space. The spinal needle (12) is extended through the epidural needle (14) to puncture the dura mater and come to rest within the subarachnoid space. A pair of concentrically disposed sliding members and a locking tab are provided to adjust the length of the needle.

B. Schaffer, U.S. Patent No. 5,429,616

Schaffer discloses "an occludable catheter apparatus for blocking the flow of blood from the catheter…" Shaffer, column 1, lines 9-11. The catheter has a clamp mechanism which serves to completely occlude the catheter, thereby preventing the flow of blood through the catheter. "This closure prevents blood from escaping while an

infusion set is connected to catheter hub 24." Shaffer, column 5, lines 17-19. As such, the catheter of Shaffer exists in two states, opened or closed.

Schaffer describes at column 5, lines 5-24 how to use the occludable catheter. With reference to Figures 1 and 2, the needle (14) enters a blood vessel. The needle (14) is removed while the catheter (40) is advanced into the lumen of the vessel. The locking members (44, 46) are engaged immediately after the needle (14) is completely withdrawn from the catheter (40) and catheter hub (24). "This closure prevents blood from escaping while an infusion set is connected to catheter hub."

Complete occlusion of the catheter is essential to the function of the Schaffer catheter. Upon removal of the needle from the catheter, capillary action will drive blood from the lumen through the catheter. Complete occlusion of the catheter will prevent this from occurring. However, if the catheter is only partially occluded, thereby reducing the effective radius of the catheter tube, the force driving blood through the catheter will be increased. Thus, a catheter will allow a greater amount of blood to backflow if the catheter tube is partially occluded then if it is not occluded at all. Therefore, complete occlusion of the catheter is a necessary result of the clamp mechanism.

2. A Prima Facie Case of Obviousness Has Not Been Established

The final office action fails to establish a *prima facie* case of obviousness. The standards for making an obviousness rejection are summarized in MPEP § 706.02(j) as follows:

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on

> applicant's disclosure. *In re Vaeck,* 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

In rejecting claims under 35 U.S.C. § 103, it is incumbent upon the Examiner to establish a factual basis to support the legal conclusion of obviousness. See *In re Fine*, 837 F.2d 1071, 1073, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). In so doing, the Examiner must make the factual determinations set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), viz., (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; and (3) the level of ordinary skill in the art. "[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a prima facie case of unpatentability." *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). Although the analysis need not identify explicit teachings directed to the claimed subject matter, "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 82 USPQ2d 1385, 1396 (2007). As such, "'there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" *Id.* (quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006)).

A person having ordinary skill and common sense in the art of spinal medication delivery would understand that it is essential to maintain a flow of medication through the spinal needle to the patient. It would be a poor choice of instruments if there was a risk of occlusion of the spinal needle during medication delivery. The claimed invention is directed toward an epidural needle set comprising a spinal needle located inside an epidural needle. The subject invention allows the clinician to adjust the length of the spinal needle protruding from within the epidural needle. Once the desired length has been established, a clamp mechanism is engaged which locks the spinal needle in place within the epidural needle, thereby fixing the amount of the spinal needle which protrudes from the epidural needle. It is essential that engagement of the clamp does not block, or occlude, the spinal needle. If the spinal needle were occluded by operation of

the clamp, medication would not be able to pass through the spinal needle, rendering the epidural needle set of the present invention unsuitable for its intended purpose.

There is no articulated reason with rational underpinning for combining an epidural needle set designed to avoid occlusion, a feature recited in the claims, with an occludable catheter. In rejecting the claims the examiner stated:

> It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the epidermal needle system as taught by McWha with the resilient member and clamp as taught by Schaffer, since such a modification would provide the epidermal needle system with the resilient member and clamp for providing inward collapsing of the side wall portion and to reduce or occlude the apparatus. (emphasis added) May 14, 2007 Office Action, page 4.

The Examiner errs in stating that it would have been obvious that the combination would allow for the reduction of the side wall portion. First of all, it is unclear what "side wall portion" is referred to in the rejection. Assuming that the "side wall portion refers" to the resilient member, the statement that the clamp would "reduce or occlude the apparatus" fails to meet the claimed limitation of "reducing, but not occluding" or "not occluded" in the claims.

An epidural needle set comprised of the combination of McWha and Schaffer would result in an apparatus with diametrically opposite function as that of the subject invention. The purpose of the Schaffer clamp is to completely occlude the catheter, thereby preventing the flow of blood through the catheter. The clamp of the subject invention is designed to reduce the size of the opening within the resilient member, without occluding the opening through the clamp. The reduction in size of the resilient member is necessary to hold the spinal needle in position while simultaneously allowing for the unrestricted flow of liquid through the needle. Therefore, the combination of McWha and Schaffer fails to teach or suggest the claimed invention.

In rejecting the claims, the examiner further maintained on pages 4-5 of the Final Office Action that if the closure has an open position and a closed position that it must

have an intermediate position, one in which the catheter is partially occluded. The Examiner further reasons that if there is an intermediate position where the catheter is partially occluded, then it would be obvious to one skilled in the art to stop closure of the clamp at a mid-point, thereby leaving the catheter in a non-occluded state. There is no suggestion or motivation to modify Shaffer in this manner because it would render the invention of Shaffer unsatisfactory for its intended use, namely occluding the catheter. It appears that the examiner is applying some form of inherency in this line of "intermediate position" reasoning.

Regarding inherency, MPEP Section 2112 states:

> The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted) (The claims were drawn to a disposable diaper having three fastening elements. The reference disclosed two fastening elements that could perform the same function as the three fastening elements in the claims. The court construed the claims to require three separate elements and held that the reference did not disclose a separate third fastening element, either expressly or inherently.). >Also, "[a]n invitation to investigate is not an inherent disclosure" where a prior art reference "discloses no more than a broad genus of potential applications of its discoveries."

It is respectfully asserted that the Examiner has failed to provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent

characteristic necessarily flows from the teachings of the applied prior art. The Examiner's contention that the clamp of Schaffer must inherently have an intermediate position is not supported by the disclosure of Schaffer and insufficient to render the present invention obvious. The flaw in the Examiner's reasoning is that a determination of inherency cannot be established by probabilities or possibilities, but it is incumbent upon the Examiner to establish the inevitability of the inherency based upon factual evidence or persuasive scientific reasoning. See *In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981), and *In re Wilding*, 535 F.2d 631 (CCPA 1976). In the present case, the Examiner has not advanced the requisite factual evidence or persuasive scientific reasoning that the use of a clamp mechanism designed to occlude a catheter passageway would work equivalently to a clamp designed to fix the position of a spinal needle within an epidural needle without occluding the spinal needle. *See Ex parte Levy,* 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original) (Applicant's invention was directed to a biaxially oriented, flexible dilation catheter balloon (a tube which expands upon inflation) used, for example, in clearing the blood vessels of heart patients). The examiner applied a U.S. patent to Schjeldahl which disclosed injection molding a tubular preform and then injecting air into the preform to expand it against a mold (blow molding). The reference did not directly state that the end product balloon was biaxially oriented. It did disclose that the balloon was "formed from a thin flexible inelastic, high tensile strength, biaxially oriented synthetic plastic material." *Id.* at 1462 (emphasis in original). The examiner argued that Schjeldahl's balloon was inherently biaxially oriented. The Board reversed on the basis that the examiner did not provide objective evidence or cogent technical reasoning to support the conclusion of inherency.). Accordingly, a *prima facie* case of obviousness has not been established.

3. The Proposed Combination Does Not Work

The Examiner has attempted to combine the teachings of McWha with Schaffer to create an epidural needle set with a mechanism for holding the spinal needle at a fixed protrusion from the epidural needle. However, the combination of McWha and Schaffer fails to result in an operative product.

Applicant respectfully points to M.P.E.P. § 2143.01(V), explaining that "[i]f proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900 (Fed. Cir. 1984) (Claimed device was a blood filter assembly for use during medical procedures wherein both the inlet and outlet for the blood were located at the bottom end of the filter assembly, and wherein a gas vent was present at the top of the filter assembly. The prior art reference taught a liquid strainer for removing dirt and water from gasoline and other light oils wherein the inlet and outlet were at the top of the device, and wherein a pet-cock (stopcock) was located at the bottom of the device for periodically removing the collected dirt and water. The reference further taught that the separation is assisted by gravity. The Board concluded the claims were prima facie obvious, reasoning that it would have been obvious to turn the reference device upside down. The court reversed, finding that if the prior art device was turned upside down it would be inoperable for its intended purpose because the gasoline to be filtered would be trapped at the top, the water and heavier oils sought to be separated would flow out of the outlet instead of the purified gasoline, and the screen would become clogged). *See* also *In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984) (finding no suggestion to modify a prior art device where the modification would render the device inoperable for its intended purpose). "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant . . . [or] if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant." *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994).

The epidural needle set of McWha allows the clinician to extend the spinal needle from within the epidural needle and lock that position by using a pair of concentrically disposed sliding members to which each of the epidural needle and spinal needle are attached. There are no compressive forces applied to the device to cause the spinal needle to be locked in place, and the sliding members must be able to move relative to

each other to permit adjustment of the spinal needle. The catheter of Schaffer uses a resilient member which can be compressed by the clamp mechanism to completely occlude the needle passageway. Adding a clamp and an occludable resilient member to McWha would produce an epidural needle set with an occluded needle passageway, and would destroy the intended function of McWha, which is to allow adjustment of the spinal needle by allowing relative motion of the sliding members. This would result in a product which would not operate. Because the resulting product produced by the combined teaching of the references would be inoperative, there is an implicit teaching away from combining these references.

H. Conclusion

Appellant submits that claims 1-20 meet the requirements for patentability under § 103. Accordingly, reversal of the Examiner's rejection is appropriate and is respectfully solicited. The undersigned was authorized by Jeanne P. Lukasavage, Reg. No. 45,172, an attorney of record in the subject application, to prepare and file this Appellant's Brief on behalf of the Assignee. Correspondence should continue to be directed to David Highet, Becton, Dickinson and Company, One Becton Drive, MC110, Franklin Lakes, New Jersey 07417-1880.

Respectfully submitted,

Dated: January 10, 2008

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I. Claims Appendix

1. An epidural needle, comprising:

an elongate tube defining a longitudinal axis having a proximal end, a distal end and an axial hollow bore having an inside diameter therethrough, wherein the distal end is a sharpened tip suitable for penetrating a patient's tissue;

a hub having a proximal end, a distal end and an open passageway therethrough, said hub being attached to the proximal end of said elongate tube so that said hollow bore of said elongate tube is in fluid communication and substantial axial alignment with said open passageway, said hub further having a cavity therein disposed between said proximal end and said distal end of said hub;

a resilient member permanently mounted within the hub having an opening therethrough defining an inner diameter and disposed in said cavity so that said opening is substantially axially aligned and in fluid communication with said open passageway; and

a clamp selectively movable between an open position wherein said inner diameter of said resilient member is substantially unaffected and a clamp position wherein said clamp causes a strain to at least a portion of said resilient member thereby reducing, but not occluding, said inner diameter of said opening through at least a portion of said resilient member.

2. The epidural needle of claim 1 wherein at least a portion of said clamp is disposed within the hub and a portion of the clamp projects outwardly from said hub to facilitate the practitioner's selective movement of said clamp between said open position and said clamp position.

3. The epidural needle of claim 2 wherein said portion of said clamp that projects outwardly from said hub further includes a releasable latch for selectively retaining said clamp in said clamp position.

4. The epidural needle of claim 3 further include a push tab extending away from the releasable latch to facilitate unclamping said clamp from said clamp position.

5. The epidural needle of claim 4 wherein the push tab is oriented for movement perpendicular to the elongate tube.

6. The epidural needle of claim 3 further including a support leg that limits movement of the latch.

7. The epidural needle of claim 1 wherein the clamp includes a pair of legs defining at least one radiused portion therein.

8. The epidural needle of claim 7 wherein the resilient member defines a radiused portion and the radiused portion of the pair of legs has a radius substantially the same as the radiused portion of the resilient member.

9. The epidural needle of claim 8 where the pair of legs defines a second radiused portion adjacent to the at least one radiused portion.

10. A combined spinal epidural needle set comprises:

an epidural needle including an elongate tube defining a longitudinal axis having a proximal end, a distal end and an axial hollow bore having an inside diameter therethrough, wherein the distal end is a sharpened tip suitable for penetrating a patient's tissue, said epidural needle having a hub having a proximal end, a distal end and an open passageway therethrough, said hub being attached to the proximal end of said elongate tube so that said hollow bore of said elongate tube is in fluid communication and substantial axial alignment with said open passageway and wherein said hub further having a cavity disposed between said proximal end and said distal end of said hub, a resilient member having an opening therethrough defining an inner diameter and disposed in said cavity so that said opening is substantially axially aligned and in fluid communication with

said open passageway, and a clamp having a releasable latch disposed about said resilient member, said clamp being selectively movable between an open position wherein said inner diameter of said resilient member is substantially unaffected and a clamp position wherein said clamp causes a strain to said resilient member thereby reducing said inner diameter of said opening through said resilient member; and

a spinal needle having an outside diameter less than said inside diameter of said hollow tube disposed within said hollow bore, and wherein a practitioner using said epidural needle to position said spinal needle may freely axially move said spinal needle within said hollow bore with respect to said epidural needle and fix a position of said spinal needle relative to said epidural needle by said reduction of said inner diameter opening through said resilient member to a diameter less than said outside diameter of the spinal needle by movement of said clamp to said clamp position thereby to grasp releasably the spinal needle sufficiently to fix the position of the spinal needle with respect to the epidural needle, wherein the spinal needle is not occluded in the clamp position.

11. The combined spinal epidural needle set of claim 10 wherein the spinal needle includes an indicia formed thereon for providing an indication to the practitioner of the location of the spinal needle with respect to the epidural needle.

12. The combined spinal epidural needle set of claim 11 wherein at least a portion of said clamp projects outwardly from said hub to facilitate the practitioner's selective movement of said clamp between said open position and said clamp position.

13. The combined spinal epidural needle set of claim 12 further including a push tab extending away from the releasable latch to facilitate unclamping said clamp from said clamp position.

14. The combined spinal epidural needle set of claim 13 wherein the push tab is oriented for movement perpendicular to the elongate tube.

15. The combined spinal epidural needle set of claim 14 further including a support leg that limits movement of the latch.

16. The combined spinal epidural needle set of claim 10 wherein the clamp includes a pair of legs defining at least one radiused portion therein.

17. The combined spinal epidural needle set of claim 16 wherein the resilient member defines a radiused portion and the radiused portion of the pair of legs has a radius substantially the same as the radiused portion of the resilient member.

18. The combined spinal epidural needle set of claim 17 where the pair of legs defines a second radiused portion adjacent to the at least one radiused portion.

19. A needle including:

an elongate tube defining a longitudinal axis having a proximal end, a distal end and an axial bore having an inside diameter therethrough, wherein the distal end is a sharpened tip;

a hub having a proximal end, a distal end and an open passageway therethrough, the hub being attached to the elongate tube so that the hollow bore of the elongate tube is in fluid communication and substantial axial alignment with the open passageway, the hub further having a cavity disposed therein between the proximal end and the distal end of the hub;

a resilient member, distinct from the elongate tube, having an opening, at least in part, therethrough defining an inner diameter and disposed in the cavity so that the opening is substantially aligned and in fluid communication with the open passageway, wherein the resilient member fixedly secured within the cavity and restrained from axial displacement with respect to the hub; and

a clamp selectively moveable between a first position wherein the resilient member is undeformed and a second position wherein the resilient member is deformed such that the inner diameter of the opening is changed through at least a

portion of the resilient member, but the inner diameter of the opening is not occluded.

20. The needle of claim 19 wherein the clamp comprises a deformable U-shaped member having an apex and two legs, wherein a living hinge is disposed at the apex and a latch is disposed on the legs for securing the legs in a relatively fixed position.

J. Evidence Appendix

None.

K. Related Proceedings Appendix

None.